| U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR) | INTERNATIONAL APPLICATION NO. | ATTORNEY'S DOCKET NUMBER |
|---|---|---|
| 10/031940 | PCT/EP00/06226 | PG3736USW |

24. The following fees are submitted:.

**BASIC NATIONAL FEE ( 37 CFR 1.492 (a) (1) - (5)) :**

| | | CALCULATIONS PTO USE ONLY |
|---|---|---|
| ☐ | Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO ..... | **$1040.00** |
| ☒ | International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... | **$890.00** |
| ☐ | International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... | **$740.00** |
| ☐ | International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... | **$710.00** |
| ☐ | International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) ..... | **$100.00** |
| | **ENTER APPROPRIATE BASIC FEE AMOUNT =** | **$890.00** |
| | Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)). | **$0.00** |

| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | |
|---|---|---|---|---|
| Total claims | 24 - 20 = | 4 | x $18.00 | **$72.00** |
| Independent claims | 2 - 3 = | 0 | x $84.00 | **$0.00** |
| Multiple Dependent Claims (check if applicable). | | | ☐ | **$0.00** |

| | | |
|---|---|---|
| **TOTAL OF ABOVE CALCULATIONS** = | | **$962.00** |
| ☐ Applicant claims small entity status. See 37 CFR 1.27). The fees indicated above are reduced by 1/2. | | **$0.00** |
| **SUBTOTAL** = | | **$962.00** |
| Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). + | | **$0.00** |
| **TOTAL NATIONAL FEE** = | | **$962.00** |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) **(check if applicable).** ☐ | | **$0.00** |
| **TOTAL FEES ENCLOSED** = | | **$962.00** |
| | **Amount to be: refunded** | $ |
| | **charged** | $ |

a. ☐ A check in the amount of _____ to cover the above fees is enclosed.

b. ☒ Please charge my Deposit Account No. **07-1392** in the amount of **$962.00** to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **07-1392** A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

SEND ALL CORRESPONDENCE TO:

23347

PATENT TRADEMARK OFFICE

SIGNATURE

**Christopher P. Rogers**

NAME

**36,334**

REGISTRATION NUMBER

22 Jan 2002

DATE

FORM PTO-1390 (Modified) (REV 11-2000) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

# TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

| ATTORNEY'S DOCKET NUMBER | U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR |
|---|---|
| PG3736USW | 10/031940 |

| INTERNATIONAL APPLICATION NO. | INTERNATIONAL FILING DATE | PRIORITY DATE CLAIMED |
|---|---|---|
| PCT/EP00/06226 | July 4, 2000 | August 7, 1999 |

TITLE OF INVENTION
**VALVE WITH A VALVE STEM WIPER**

APPLICANT(S) FOR DO/EO/US
**WALKER, Richard Ian**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include itens (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☒ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

**Items 13 to 20 below concern document(s) or information included:**

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
22. ☒ Certificate of Mailing by Express Mail
23. ☒ Other items or information:

**Copy of PCT Request**
**Copy of PCT Cover Sheet**



Express Mail Label No.:
EL395941384US

US Serial No.: nya
Applicant Docket No.: PG3736USW
Int'l Appln. No.: PCT/EP00/06226

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | |
|---|---|
| In re Appln. of: Walker, Richard Ian | |
| USPTO Serial No.: NYA | Examiner: NYA<br>Art Unit: NYA |
| USPTO Filing Date: Concurrently Herewith | Docket No.: PG3736USW |
| Int'l Application No.: PCT/EP00/06226 | |
| Int'l Filing Date: 4 July 2000 | |
| Title: Valve | |

Attention: Box PCT/DO/EO/US

PRELIMINARY AMENDMENT UNDER 35 USC 111

Commissioner for Patents
Washington D.C. 20231

Sir:

The above identified application is being transmitted herewith for entry into the U.S. National Phase under Chapter II of the PCT. For the purposes of adding the priority information, kindly amend the application as follows.

**In the Abstract:**

Kindly substitute the attached Abstract, which as been placed on a separate sheet in accordance with U.S. practice.

**In the Specification:**

On the first line of the specification, after the Title, kindly add:

--This application is filed pursuant to 35 U.S.C. § 371 as a United States National Phase Application of International Application No. PCT/EP00/06226 filed July 4, 2000, which claims priority from GB 9918627.2 filed August 7, 1999.--.

## In the Claims:

Kindly amend the claims as follows. Marked-up and clean versions of the new and amended claims is provided herein. Kindly substitute the clean version of the amended claims for the corresponding pending claims.

## VERSION WITH MARKINGS SHOWING CHANGES MADE TO CLAIMS

1. (Amended) [Valve for an aerosol container, the] A valve comprising:

a valve body defining a metering chamber in communication with a dispensing passage; and,

a valve stem having [a] the dispensing passage and a transfer passage [, and] contacting [said valve stem,] and slidably movable with respect to

a first sealing ring including a first sealing portion;

[the valve stem being slidably movable relative to the sealing ring from a valve-closed position to a valve-open position in which the interior of the valve body is in communication with the dispensing passage,]

wherein the sealing ring further includes a first wiper adapted to wipe the valve stem.

2. (Amended) [Valve] The valve according to claim 1, [wherein the valve body has a metering chamber,] further including:

a sampling chamber; and, [and therebetween is provided]

a second sealing ring[,] including a second sealing portion, [within which the stem is slidably movable, the valve stem having a transfer passage such that]

wherein, in [the] a valve-closed position, the dispensing is isolated from the metering chamber and the metering chamber is in communication with the sampling chamber via said transfer passage, [and]

wherein, in the valve-open position, the dispensing passage is in communication with the metering chamber and the transfer passage is isolated from the metering chamber, and,

wherein the second sealing ring further includes a second wiper adapted to wipe the valve stem.

3. (Amended) [Valve] The valve according to [either of claims 1 or 2] claim 1, wherein the first and/or second wiper is [an] integral [part of the sealing ring or] to the first and/or second sealing ring, respectively.

4. (Amended) [Valve] The valve according to [any of claims 1 to 3] claim 2, wherein the first and/or second wiper [of the sealing ring or second sealing ring is in curved contact with the valve stem] includes first and/or second curved portions, respectively.

5. (Amended) [Valve] The valve according to [any of claims 1 to 4] claim 4, [wherein there is] including an enclosed space between the first and/or second wiper[, the sealing portion and the seal-receiving part of] and the valve stem.

6. (Amended) [Valve] The valve according to [any of claims 1 to 5] claim 5, wherein the [stem-receiving parts of the seal and wiper have] first and/or second sealing portions include first and/or second square cut edges, respectively.

7. (Amended) [Valve] The valve according to [any of claims 1 to 5] claim 2 wherein the [stem-receiving parts of the seal and wiper] first and/or second sealing portions [have] include first and/or second rounded edges, respectively.

8. (Amended) [Valve] The valve according to [any of claims 1 to 5] claim 2, wherein the [stem-receiving part of the] first and/or second wiper [is] includes first and/or second tapered portions, respectively [pointed].

9. (Amended) [Valve] The valve according to [any of claims 1 to 8] claim 2, [wherein the seal and wiper are spaced by a] further including a first and/or second layer of [supporting] rigid material supporting the first and/or second wiper and sealing portion, respectively.

10. (Amended) [Valve] The valve according to claim 9 wherein [said] the first and/or second layer [rigid material] is constructed from a material selected

from the group consisting of a polybutylteraphthlate, polyoxymethylene, [a] metal and nylon.

11. (Amended) [Valve] The valve according to [any of claims 1 to 10] claim 2, wherein the [stem receiving part of the seal is] first and/or second sealing portions include first and/or second lobed portions, respectively.

Kindly cancel claim 12.

13. (Amended) [Valve] The valve according to [any of claims 1 to 12] claim 2, wherein the first and/or second sealing ring [and/or second sealing ring is formable by a] constructed by moulding [process].

14. (Amended) [Valve] The valve according to claim 13 wherein the [moulding process] first and/or second sealing ring is made by compression moulding or injection moulding.

15. (Amended) [Valve] The valve according to [any of claims 1 to 14] claim 2, wherein the first and/or second sealing ring[, second sealing ring and wiper are] is formed from an elastomeric material.

16. (Amended) [Valve] The valve according to claim 15 wherein [said] the elastomeric material is selected from the group consisting of:

[(a) a thermoplastic elastomer comprising] a copolymer of about 80 to about 95 [percent] mole% ethylene and [a total of] about 5 to about 20 [percent mole percent] mole% of one or more of 1-butene, 1-hexene and 1-octene;

[(b)] a styrene-ethylene/butylene-styrene block copolymer;

[(c)] an ethylene propylene diene rubber [(EPDM)];

[(d) a thermoplastic elastomer blend of EPDM] a styrene-ethylene/butylene-styrene dispersed in a polypropylene or polyethylene matrix;

[(e)] a butyl polyethylene;

[(f)] a butyl-polypropylene; and

[any] mixtures thereof.

17. (Amended) [Valve] The valve according to [any of claims 1 to 16] claim 2, wherein the [sealing ring] first and/or second sealing ring is [not movable] fixed relative to the valve body.

18. (Amended) [Valve] The valve according to claim 17, wherein the [sealing ring] first and/or second sealing ring is [held] fixed within a cavity in the valve body.

19. (Amended) [Valve] The valve according to [any of claims 1 to 18] claim 1, wherein the stem [comprises] includes a lubricant [material].

20. (Amended) [Valve] The valve according to [any of claims 1 to 19] claim 1, wherein the [sealing ring] first and/or second sealing ring [comprises] includes a lubricant [material].

21. (Amended) A drug product comprising:

an aerosol [Aerosol] container [comprising a valve according to any of claims 1 to 20] in communication with

a valve body defining a metering chamber in communication with a dispensing passage; and,

a valve stem having the dispensing passage and a transfer passage contacting and slidably movable with respect to

a first sealing ring including a first sealing portion;

wherein the sealing ring further includes a first wiper adapted to wipe the valve stem.

22. (Amended) The drug product of claim 21, [Aerosol container according to claim 21] further comprising a suspension of a medicament in a propellant contained within the aerosol container.

23. (Amended) [Aerosol container] The drug product according to claim 22, wherein[,] the propellant is liquified HFA134a or HFA-227 [and] or mixtures thereof.

24. (Amended) [Aerosol container] The drug product according to [either of claims 22 or 23] claim 22, wherein the medicament is selected from the group consisting of albuterol, salmeterol, fluticasone [propionate], beclomethasone [dipropionate], salts, esters or solvates thereof, and [any combination] combinations thereof.

25. (Amended) [Aerosol container] The drug product according to claim 24 wherein [said combination] the medicament comprises salmeterol xinafoate and fluticasone propionate.

## CLEAN VERSION OF THE NEW AND AMENDED CLAIMS

1. (Amended) A valve comprising:

a valve body defining a metering chamber in communication with a dispensing passage; and,

a valve stem having the dispensing passage and a transfer passage contacting and slidably movable with respect to

a first sealing ring including a first sealing portion;

wherein the sealing ring further includes a first wiper adapted to wipe the valve stem.

2. (Amended) The valve according to claim 1, further including:

a sampling chamber; and,

a second sealing ring including a second sealing portion,

wherein, in a valve-closed position, the dispensing is isolated from the metering chamber and the metering chamber is in communication with the sampling chamber via said transfer passage,

wherein, in the valve-open position, the dispensing passage is in communication with the metering chamber and the transfer passage is isolated from the metering chamber, and,

wherein the second sealing ring further includes a second wiper adapted to wipe the valve stem.

3. (Amended) The valve according to claim 1, wherein the first and/or second wiper is integral to the first and/or second sealing ring, respectively.

4. (Amended) The valve according to claim 2, wherein the first and/or second wiper includes first and/or second curved portions, respectively.

5. (Amended) The valve according to claim 4, including an enclosed space between the first and/or second wiper and the valve stem.

6. (Amended) The valve according to claim 5, wherein the first and/or second sealing portions include first and/or second square cut edges, respectively.

7. (Amended) The valve according to claim 2 wherein the first and/or second sealing portions include first and/or second rounded edges, respectively.

8. (Amended) The valve according to claim 2, wherein the first and/or second wiper includes first and/or second tapered portions, respectively.

9. (Amended) The valve according to claim 2, further including a first and/or second layer of rigid material supporting the first and/or second wiper and sealing portion, respectively.

10. (Amended) The valve according to claim 9 wherein the first and/or second layer is constructed from a material selected from the group consisting of a polybutylteraphthlate, polyoxymethylene, metal and nylon.

11. (Amended) The valve according to claim 2, wherein the first and/or second sealing portions include first and/or second lobed portions, respectively.

13. (Amended) The valve according to claim 2, wherein the first and/or second sealing ring constructed by moulding.

14. (Amended) The valve according to claim 13 wherein the first and/or second sealing ring is made by compression moulding or injection moulding.

15. (Amended) The valve according to claim 2, wherein the first and/or second sealing ring is formed from an elastomeric material.

16. (Amended) The valve according to claim 15 wherein the elastomeric material is selected from the group consisting of:

a copolymer of about 80 to about 95 mole% ethylene and about 5 to about 20 mole% of one or more of 1-butene, 1-hexene and 1-octene;

a styrene-ethylene/butylene-styrene block copolymer;

an ethylene propylene diene rubber;

a styrene-ethylene/butylene-styrene dispersed in a polypropylene or polyethylene matrix;

a butyl polyethylene;

a butyl-polypropylene; and

mixtures thereof.

17. (Amended) The valve according to claim 2, wherein the first and/or second sealing ring is fixed relative to the valve body.

18. (Amended) The valve according to claim 17, wherein the first and/or second sealing ring is fixed within a cavity in the valve body.

19. (Amended) The valve according to claim 1, wherein the stem includes a lubricant.

20. (Amended) The valve according to claim 1, wherein the first and/or second sealing ring includes a lubricant.

21. (Amended) A drug product comprising:

an aerosol container in communication with

a valve body defining a metering chamber in communication with a dispensing passage; and,

a valve stem having the dispensing passage and a transfer passage contacting and slidably movable with respect to

a first sealing ring including a first sealing portion;

wherein the sealing ring further includes a first wiper adapted to wipe the valve stem.

22. (Amended) The drug product of claim 21, further comprising a suspension of a medicament in a propellant contained within the aerosol container.

23. (Amended) The drug product according to claim 22, wherein the propellant is liquified HFA134a or HFA-227 or mixtures thereof.

24. (Amended) The drug product according to claim 22, wherein the medicament is selected from the group consisting of albuterol, salmeterol, fluticasone, beclomethasone, salts, esters or solvates thereof, and combinations thereof.

25. (Amended) The drug product according to claim 24 wherein the medicament comprises salmeterol xinafoate and fluticasone propionate.

## REMARKS

Claims 1-11 and 13-25 are pending. Claim 12 has been cancelled without prejudice to the filing of subsequent claims directed to the subject matter therein. The claims have been amended to more appropriately conform to U.S. practice and to reduce the filing fee by deleting multiple dependencies. Applicants further attach on a separate sheet an Abstract as required by U.S. practice. Applicants have also amended the specification to add the priority information.

The claims have been amended to more broadly and comprehensively particularly point out and distinctly claim the subject matter applicant regards as the invention. Support for the amendments is found in the application as originally filed. No new matter has been added. A favorable first action on the merits is solicited.

Respectfully submitted,

Date: 22 Jan 2002

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Express Mail Label No.:
EL395941384US

# VALVE WITH A VALVE STEM WIPER

## Field of invention

This invention relates to a valve for an aerosol container with the aid of which a quantity of the contents thereof can be dispensed. The invention has particular application to the dispensing of metered doses of medicaments, though it is applicable to the dispensing of aerosols generally.

## Background to the invention

Containers for aerosol formulations commonly comprise a vial body coupled to a valve. The valve comprises a valve stem through which the formulation is dispensed. Generally the valve includes a rubber valve seal intended to allow reciprocal movement of the valve stem while preventing leakage of propellant from the container.

It has been found that in some conventional devices the valve stem tends to drag during the actuation cycle with the result that the user may perceive a 'notchiness' as the valve stem is depressed and released. This may be partly caused by the drug sedimenting or precipitating out of the drug-propellant suspension or solution formulation and depositing on the internal valve components, the presence of drug on the sliding interface creating increased friction during operation.

The Applicants have now found that the above described problem of notchiness may be ameliorated without compromising sealing performance if the valve seal has a wiper component in addition to a sealing portion. The wiper acts on the valve stem to prevent the deposit and accumulation of drug particles and propellant at the point of contact between the sealing portion and the valve stem. The 'notchiness' that can increase with repeated actuations of the aerosol container is therefore reduced.

Any 'notchiness' may be further reduced by shaping the seal so as to reduce the area of contact between the seal and the valve stem. This results in reduced deformation of the seal and a reduction in the friction at the contact point with the valve stem.

## Summary of the invention

According to one aspect of the present invention there is provided a valve for an aerosol container, the valve comprising a valve body; a valve stem having a dispensing passage, and contacting said valve stem, a sealing ring including a sealing portion; the valve stem being slidably movable relative to the sealing ring from a valve-closed position to a valve-open position in which the interior of the valve body is in communication with the dispensing passage, wherein the sealing ring further includes a wiper to wipe the valve stem.

Preferably the valve body has a metering chamber, a sampling chamber and therebetween is provided a second sealing ring, including a sealing portion, within which the stem is slidably movable, the valve stem having a transfer passage such that in the valve-closed position the dispensing passage is isolated from the metering chamber and the metering chamber is in communication with the sampling chamber via said transfer passage, and in the valve-open position the dispensing passage is in communication with the

metering chamber and the transfer passage is isolated from the metering chamber, wherein the second sealing ring further includes a wiper to wipe the valve stem.

The wiper is typically longer and thinner than the sealing portion of the sealing ring and second sealing ring. The wiper acts to wipe drug deposits away from the stem and does not itself have a primary sealing role.

Preferably the wiper is an integral part of the sealing ring or second sealing ring.

Preferably the wiper of the sealing ring or second sealing ring is in curved contact with the valve stem.

Preferably there is an enclosed space between the wiper, the sealing portion and the seal receiving part of the valve stem.

In one aspect the stem-receiving part of the sealing portion and wiper have square-cut edges.

In another aspect the stem-receiving parts of the sealing portion and wiper have rounded edges.

In a further aspect the stem-receiving part of the wiper is pointed.

In one aspect the sealing portion and wiper are spaced by a layer of supporting rigid material.

Preferably said rigid material is selected from the group consisting of polybutylteraphthlate, polyoxymethylene, a metal and nylon. Suitable metals include stainless steel and aluminium.

In one aspect of the invention the stem-receiving part of the sealing portion is lobed.

Optionally the sealing ring additionally includes a second wiper.

Preferably the sealing ring and second sealing ring are formable by a moulding process. Preferably the moulding process is compression moulding or injection moulding.

Preferably the sealing ring, second sealing ring and wiper are formed from an elastomeric material.

The elastomeric material may either comprise a thermoplastic elastomer (TPE) or a thermoset elastomer which may optionally be cross-linked. The sealing ring and/or second sealing ring may also comprise a thermoplastic elastomer blend or alloy in which an elastomeric material is dispersed in a thermoplastic matrix. The elastomers may optionally additionally contain conventional polymer additives such as processing aids, colorants, tackifiers, lubricants, silica, talc, or processing oils such as mineral oil in suitable amounts.

Suitable thermoset rubbers include butyl rubbers, chloro-butyl rubbers, bromo-butyl rubbers, nitrile rubbers, silicone rubbers, flurosilicone rubbers, fluorocarbon rubbers, polysulphide rubbers, polypropylene oxide rubbers, isoprene rubbers, isoprene-isobutene rubbers, isobutylene rubbers or neoprene (polychloroprene) rubbers.

Suitable thermoplastic elastomers comprise a copolymer of about 80 to about 95 mole percent ethylene and a total of about 5 to about 20 mole percent of one or more comonomers selected from the group consisting of 1-butene, 1-hexene, and 1-octene as known in the art. Two or more such copolymers may be blended together to form a thermoplastic polymer blend.

Another suitable class of thermoplastic elastomers are the styrene-ethylene/ butylene-styrene block copolymers. These copolymers may additionally comprise a polyolefin (e.g. polypropylene) and a siloxane.

Thermoplastic elastomeric material may also be selected from one or more of the following: polyester rubbers, polyurethane rubbers, ethylene vinyl acetate rubber, styrene butadiene rubber, copolyether ester TPE, olefinic TPE, polyester amide TPE and polyether amide TPE.

Other suitable elastomers include ethylene propylene diene rubber (EPDM). The EPDM may be present on its own or present as part of a thermoplastic elastomer blend or alloy, e.g. in the form of particles substantially uniformly dispersed in a continuous thermoplastic matrix (e.g. polypropylene or polyethylene). Commercially available thermoplastic elastomer blend and alloys include the SANTOPRENE™ elastomers. Other suitable thermoplastic elastomer blends include butyl-polyethylene (e.g. in a ratio ranging between about 2:3 and about 3:2) and butyl-polypropylene.

Preferably the sealing ring and/or second sealing ring is not movable relative to the valve body. More preferably the sealing ring and/or second sealing ring is held within a cavity in the valve body.

Preferably the stem comprises lubricant material. Suitably the valve stem comprises up to 30%, preferably from 5 to 20% lubricant material.

Preferably the sealing ring and/or second sealing ring comprises lubricant material. Suitably, the sealing ring and/or second sealing ring comprise up to 30%, preferably from 5 to 20% lubricant material.

According to another aspect of the present invention there is provided an aerosol container comprising a valve as described hereinabove.

Preferably the aerosol container comprises a suspension of a medicament in a propellant. Preferably the propellant is liquefied HFA134a or HFA-227.

Preferably the medicament is selected from the group consisting of albuterol, salmeterol, fluticasone propionate, beclomethasone dipropionate, salts or solvates thereof and any combination thereof.

A particularly preferred combination comprises salmeterol xinafoate and fluticasone propionate.

**Brief description of the drawings**

The invention will now be described further with reference to the accompanying drawings in which:

Figure 1 is a section through a prior art metering valve;

Figure 2a and 2b are close up sectional views of a seal-stem contact point in a valve according to the invention, showing two different arrangements and shapes of the sealing portion and wiper of the sealing ring or second sealing ring.

**Detailed description of the drawings**

A prior art metering valve is shown in Figure 1 and comprises a valve body 1 sealed in a ferrule 2 by means of crimping, the ferrule itself being set on the neck of a container (not shown) with interposition of a gasket 3 in a well-known manner. The container is loadable with a suspension of medicament, such as salmeterol xinafoate in liquid propellant HFA134a.

The valve body 1 is formed at its lower part with a metering chamber 4, and its upper part with a sampling chamber 5 which also acts as a housing for a return spring 6. The words "upper" and "lower" are used for the container when it is in a use orientation with the neck of the container and valve at the lower end of the container which corresponds to the orientation of the valve as shown in Figure 1. Inside the valve body 1 is disposed a valve stem 7, a part 8 of which extends outside the valve through lower stem seal 9 and ferrule 2. The stem part 8 is formed with an inner axial or longitudinal canal 10 opening at the outer end of the stem and in communication with a radial passage 11.

The upper portion of stem 7 has a diameter such that it can pass slidably through an opening in an upper stem seal 12 and will engage the periphery of that opening sufficiently to provide a seal. Upper stem seal 12 is held in position against a step 13 formed in the valve body 1 between the said lower and upper parts by a sleeve 14 which defines the metering chamber 4 between lower stem seal 9 and upper stem seal 12. The valve stem 7 has a passage 15 which, when the stem is in the inoperative position shown, provides a communication between the metering chamber 4 and sampling chamber 5, which itself communicates with the interior of the container via orifice 16 formed in the side of the valve body 1.

Valve stem 7 is biased downwardly to the inoperative position by return spring 6 and is provided with a shoulder 17, which abuts, against lower stem seal 9. In the inoperative position as shown in Figure 1 shoulder 17 abuts against lower stem seal 9 and radial passage 11 opens below lower stem seal 9 so that the metering chamber 4 is isolated from canal 10 and suspension inside cannot escape.

A ring 18 having a "U" shaped cross section extending in a radial direction is disposed around the valve body below orifice 16 so as to form a trough 19 around the valve body. As seen in Figure 1 the ring is formed as a separate

component having an inner annular contacting rim of a diameter suitable to provide a friction fit over the upper part of valve body 1, the ring seating against step 13 below the orifice 16. However, the ring 18 may alternatively be formed as an integrally moulded part of valve body 1.

To use the device the container is first shaken to homogenise the suspension within the container. The user then depresses the valve stem 7 against the force of the spring 6. When the valve stem is depressed both ends of the passage 15 come to lie on the side of upper stem seal 12 remote from the metering chamber 4. Thus a dose is metered within the metering chamber. Continued depression of the valve stem will move the radial passage 11 into the metering chamber 4 while the upper stem seal 12 seals against the valve stem body. Thus, the metered dose can exit through the radial passage 11 and the outlet canal 10.

Releasing the valve stem causes it to return to the illustrated position under the force of the spring 6. The passage 15 then once again provides communication between the metering chamber 4 and sampling chamber 5. Accordingly, at this stage liquid passes under pressure from the container through orifice 16, through the passage 15 and thence into the metering chamber 4 to fill it.

Figure 1 illustrates a prior art valve with square cut valve seals while the current invention describes the use of a wiper seal to wipe the valve stem and consequently reduce the 'notchiness' during actuation of the inhaler device. The wiper and sealing portion of the sealing ring replace the square cut seals (9 and 12) shown in Figure 1. The detail of the wiper and sealing portion of the sealing ring according to the invention are described below and illustrated in Figures 2a and 2b.

Figure 2a shows upright valve stem 108, which has a circular cross-section. A sealing ring 112 sealingly contacts the valve stem 108. The sealing ring 112 is comprised, at the stem receiving part, of a sealing portion 120 and a wiper 130.

The wiper 130 is in curved contact with the valve stem 108 and is separated from the sealing portion 120 by an enclosed space 140. The wiper 130 wipes the valve stem 108 so that any particles are wiped away from the sealing portion 120 of the sealing ring 112. The wiper does not have a sealing function. The wiper 130 is long and thin in comparison to the sealing portion 120 and the length of the wiper 130 may be varied for optimum performance

Figure 2b shows upright valve stem 208, which has a circular cross section. A sealing ring 212 sealingly contacts the valve stem 208. The sealing ring 212 is comprised, at the stem-receiving part, of a sealing portion 220 and a wiper 230. The wiper 230 and sealing portion 220 are separated at the stem receiving part by a small enclosed space 240 and are supported by a layer of rigid material 250. The wiper 230 wipes the valve stem 208 so that any particles are wiped away from the sealing portion 220 of the sealing ring 212. The wiper 230 is long and thin in comparison to the sealing portion 220 and the length of the wiper 230 may be varied for optimum performance. The supporting layer of rigid material 250 supports the sealing portion 220 and wiper 230 and reduces the deformation of the sealing portion 220 during movement of the valve stem 208. The supporting layer thereby reduces the surface contact area between the sealing portion 220 and the valve stem 208 and consequently further reduces the problem of 'notchiness'.

The aerosol container and valve of the invention is suitable for dispensing medicament, particularly for the treatment of respiratory disorders. Medicaments which may be administered in the aerosol formulations include any drug useful in inhalation therapy. Appropriate medicaments may thus be selected from, for example, analgesics, e.g. codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g. diltiazem; antiallergics, e.g. cromoglycate, ketotifen or nedocromil; antiinfectives e.g. cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g. methapyrilene; anti-inflammatories, e.g. beclomethasone, flunisolide,

budesonide, tipredane, triamcinolone acetonide, fluticasone or mometasone; antitussives, e.g. noscapine; bronchodilators, e.g. ephedrine, epinephrine, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimiterol, salbutamol, salmeterol, terbutaline, isoetharine, tulobuterol, 4-hydroxy-7-[2-[[2-[[3-(2-phenylethoxy)propyl]sulfonyl]ethyl]amino]ethyl-2(3H)-benzothiazolone; orciprenaline, or (-)-4-amino-3,4-dichloro-α-[[[6-[2-(2-pyridinyl)ethoxy]hexyl]amino] methyl]benzenemethanol; diuretics, e.g. amiloride; anticholinergics e.g. ipratropium, atropine or oxitropium; hormones, e.g. cortisone, hydrocortisone or prednisolone; xanthines e.g. aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; and therapeutic proteins and peptides, e.g. insulin or glucagon. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts (e.g. as alkali metal or amine salts or as acid addition salts) or as esters (e.g. lower alkyl esters) or as solvates (e.g. hydrates) to optimize the activity and/or stability of the medicament and/or to minimize the solubility of the medicament in the propellant. It will further be clear to a person skilled in the art that where appropriate, the medicaments may be used in the form of a pure isomer, for example, R-salbutamol or RR formoterol.

Particularly preferred medicaments for administration using aerosol formulations in accordance with the invention include anti-allergics, bronchodilators and anti-inflammatory steroids of use in the treatment of respiratory disorders such as asthma by inhalation therapy, for example cromoglycate (e.g. as the sodium salt), salbutamol (e.g. as the free base or the sulphate salt), salmeterol (e.g. as the xinafoate salt), formoterol (e.g. as the fumarate salt), terbutaline (e.g. as the sulphate salt), reproterol (e.g. as the hydrochloride salt),a beclomethasone ester (e.g. the dipropionate), a fluticasone ester (e.g. the propionate). Salmeterol, especially salmeterol xinafoate, salbutamol, fluticasone propionate, beclomethasone dipropionate and physiologically acceptable salts and solvates thereof are especially preferred.

It will be appreciated by those skilled in the art that the aerosol formulations according to the invention may, if desired, contain a combination of two or more active ingredients. Aerosol compositions containing two active ingredients are known for the treatment of respiratory disorders such as asthma, for example, formoterol and budesonide, salmeterol (e.g. as the xinafoate salt) and fluticasone (e.g. as the propionate ester), salbutamol and beclomethasone (as the dipropionate ester) are preferred.

The term 'lubricant' herein means any material that reduces friction between the valve stem and seal or reduces the tendency of medicament to adhere to any parts of the metering valve which contact the medicament suspension. Suitable lubricants include fluoropolymers such as polytetrafluoroethylene (PTFE), fluoroethylene propylene (FEP), polyfluoro-cyclohexane, polyfluoro-hexane, trifluoroethylene, vinylidene fluoride and vinyl fluoride. Other suitable inorganic coatings which may be used to reduce adherence or which enhance the barrier properties to HFA134a, moisture, or drug absorption, include silicone oil or siloxanes such as dimethyl siloxane. Any movable parts may also have coatings applied thereto, which enhance their desired movement characteristics. Frictional coatings may therefore be applied to enhance frictional contact and lubricants used to reduce frictional contact as necessary.

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations, and improvements thereto.

The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such a subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following claims:

## Claims

1. Valve for an aerosol container, the valve comprising a valve body; a valve stem having a dispensing passage, and contacting said valve stem, a sealing ring including a sealing portion; the valve stem being slidably movable relative to the sealing ring from a valve-closed position to a valve-open position in which the interior of the valve body is in communication with the dispensing passage, wherein the sealing ring further includes a wiper to wipe the valve stem.

2. Valve according to claim 1, wherein the valve body has a metering chamber, a sampling chamber and therebetween is provided a second sealing ring, including a sealing portion, within which the stem is slidably movable, the valve stem having a transfer passage such that in the valve-closed position the dispensing passage is isolated from the metering chamber and the metering chamber is in communication with the sampling chamber via said transfer passage, and in the valve-open position the dispensing passage is in communication with the metering chamber and the transfer passage is isolated from the metering chamber, wherein the second sealing ring further includes a wiper to wipe the valve stem.

3. Valve according to either of claims 1 or 2 wherein the wiper is an integral part of the sealing ring or second sealing ring.

4. Valve according to any of claims 1 to 3 wherein the wiper of the sealing ring or second sealing ring is in curved contact with the valve stem.

5. Valve according to any of claims 1 to 4 wherein there is an enclosed space between the wiper, the sealing portion and the seal-receiving part of the valve stem.

6. Valve according to any of claims 1 to 5 wherein the stem-receiving parts of the seal and wiper have square cut edges.

7. Valve according to any of claims 1 to 5 wherein the stem-receiving parts of the seal and wiper have rounded edges.

8. Valve according to any of claims 1 to 5 wherein the stem-receiving part of the wiper is pointed.

9. Valve according to any of claims 1 to 8 wherein the seal and wiper are spaced by a layer of supporting rigid material.

10. Valve according to claim 9 wherein said rigid material is selected from the group consisting of polybutylteraphthlate, polyoxymethylene, a metal and nylon.

11. Valve according to any of claims 1 to 10 wherein the stem receiving part of the seal is lobed.

12. Valve according to any of claims 1 to 11 additionally comprising a second wiper.

13. Valve according to any of claims 1 to 12, wherein the sealing ring and/or second sealing ring is formable by a moulding process.

14. Valve according to claim 13 wherein the moulding process is compression moulding or injection moulding.

15. Valve according to any of claims 1 to 14, wherein the sealing ring, second sealing ring and wiper are formed from an elastomeric material.

16. Valve according to claim 15 wherein said elastomeric material is selected from the group consisting of:

(a) a thermoplastic elastomer comprising a copolymer of about 80 to about 95 percent ethylene and a total of about 5 to about 20 percent mole percent of one or more of 1-butene, 1-hexene and 1-octene;

(b) a styrene-ethylene/butylene-styrene block copolymer;

(c) an ethylene propylene diene rubber (EPDM);

(d) a thermoplastic elastomer blend of EPDM dispersed in a polypropylene or polyethylene matrix;

(e) a butyl polyethylene;

(f) butyl-polypropylene; and any mixtures thereof.

17. Valve according to any of claims 1 to 16, wherein the sealing ring and/or second sealing ring is not movable relative to the valve body.

18. Valve according to claim 17, wherein the sealing ring and/or second sealing ring is held within a cavity in the valve body.

19. Valve according to any of claims 1 to 18, wherein the stem comprises lubricant material.

20. Valve according to any of claims 1 to 19 wherein the sealing ring and/or second sealing ring comprises lubricant material.

21. Aerosol container comprising a valve according to any of claims 1 to 20.

22. Aerosol container according to claim 21 comprising a suspension of a medicament in a propellant.

23. Aerosol container according to claim 22, wherein, the propellant is liquefied HFA134a or HFA-227 and mixtures thereof.

24. Aerosol container according to either of claims 22 or 23, wherein the medicament is selected from the group consisting of albuterol, salmeterol, fluticasone propionate, beclomethasone dipropionate, salts or solvates thereof and any combination thereof.

25. Aerosol container according to claim 24 wherein said combination comprises salmeterol xinafoate and fluticasone propionate.

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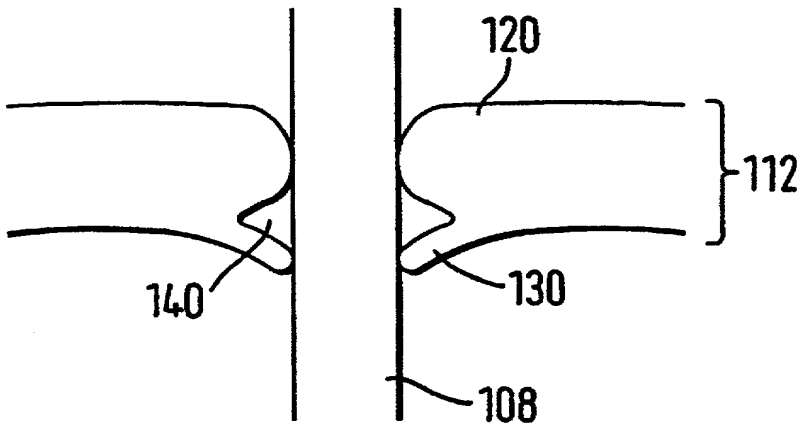
(54) Title: VALVE WITH A VALVE STEM WIPER




(57) Abstract: There is provided a valve for an aerosol container. The valve comprises a valve body (1); a valve stem (7) having a dispensing passage (15), and contacting said valve stem (7), a sealing ring (9, 12) including a sealing portion; the valve stem (7) being slidably movable relative to the sealing ring (9, 12) from a valve-closed position to a valve-open position in which the interior of the valve body is in communication with the dispensing passage (15). The sealing ring (9, 12) further includes a wiper (130) to wipe the valve stem. Preferably, the valve is a metering valve.

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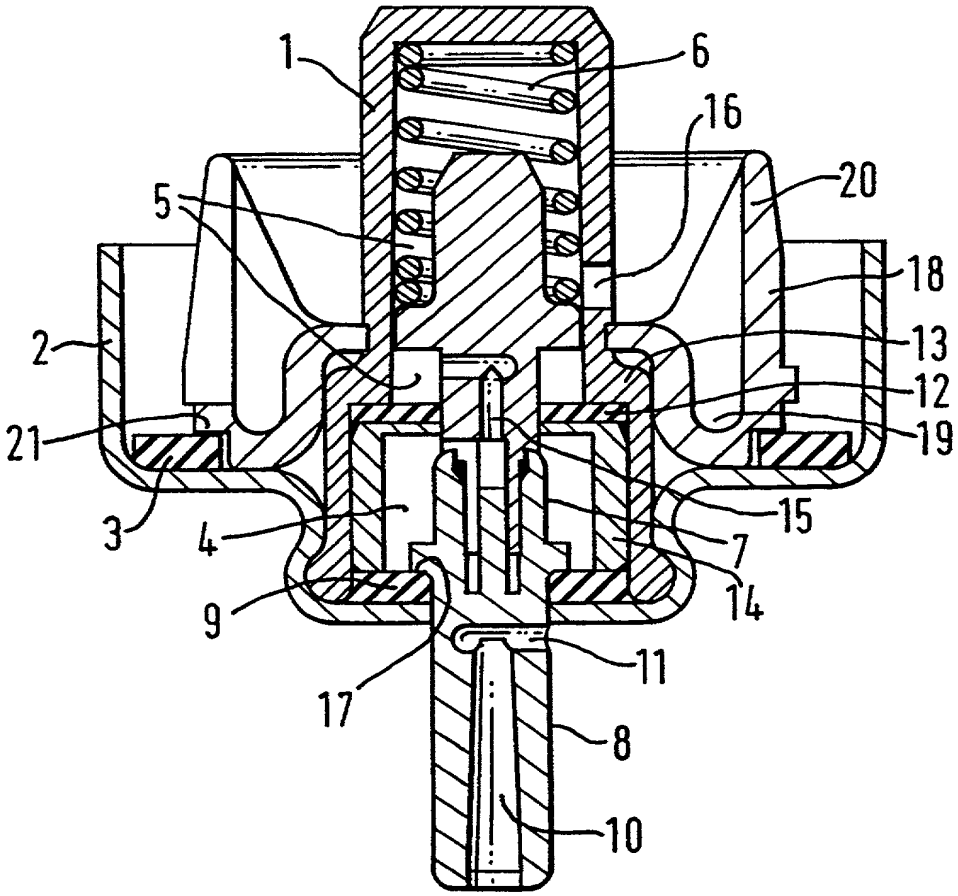


FIG. 1

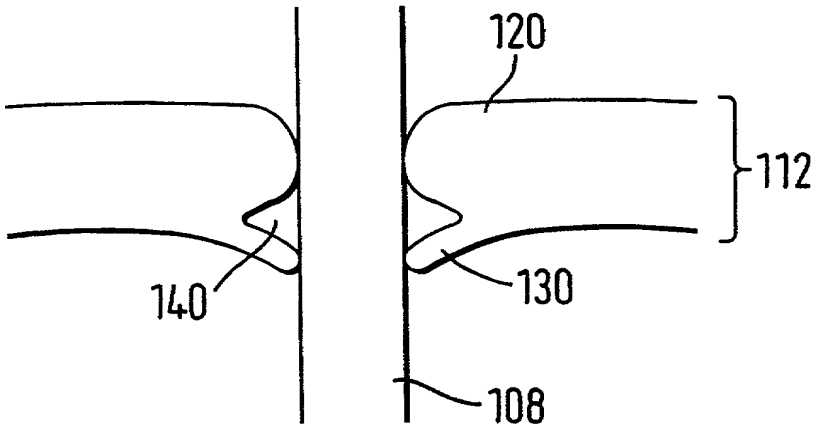


FIG. 2a

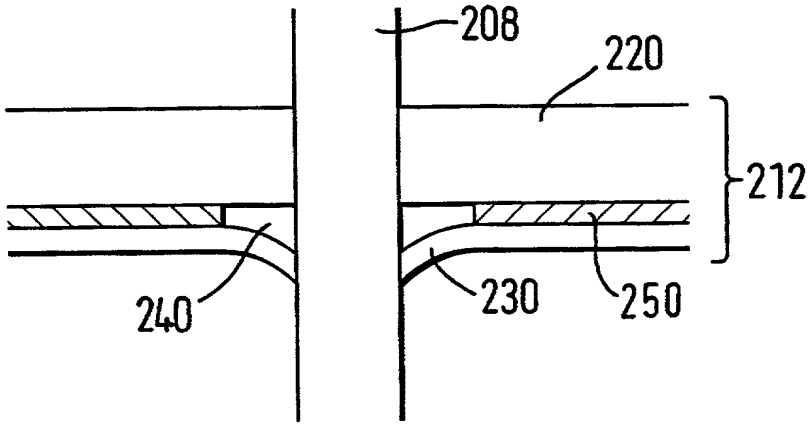


FIG. 2b

# COMBINED DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION WITH POWER OF ATTORNEY

| ATTORNEY'S DOCKET |
|---|
| PG3736USW |
| First Names Inventor: Richard Ian WALKER |
| ***Complete if known:*** App No.: |
| Filing Date |
| Group Art Unit: |

( ) Declaration submitted with initial filing or

( )Declaration submitted after initial filing (surcharge required 37CFR1.16(e))

As below named inventor. I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**VALVE WITH A VALVE STEM WIPER**

the specification of which (check only one item below):

[ ]is attached hereto.

OR

[ x ] was filed on **4 July 2000** as United States application Serial No. _____ or **PCT** International

Application Number **PCT/EP00/06226** filed and was amended on (MM/DD/YYYY) _____(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56.

I hereby claim foreign priority benefits under 35, U.S.C. §119 (a)-(d) or §365(b) of any foreign applications(s) for patent or inventor's certificate or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or of any PCT international application having a filing date before that of the application on which priority is claimed:

**PRIOR FOREIGN AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:**

| Prior Foreign Application Number (s) | Country | Foreign Filing Date (MM/DD/YYYY)) | PRIORITY CLAIMED |
|---|---|---|---|
| 1 9918627.2 | GB | 08/07/1999 | X |
| 2. | | | |
| 3. | | | |
| 4. | | | |
| 5. | | | |

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below:

| Application No. | Filing Date (MM/DD/YYYY) | |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |

# COMBINED DECLARATION FOR UTILITY or DESIGN PATENT APPLICATION WITH POWER OF ATTORNEY Continued

ATTORNEY'S DOCKET NUMBER: PG3736USW

I hereby claim the benefit under 35, U.S.C. §120 of any United States application or §365(c) of any PCT international application designating the United States of America that is listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56 which became available between the filing date of the prior application(s) and the national or PCT international filing date of this application:

## PRIOR U.S. PARENT APPLICATION or PCT PARENT APPLICATION

| U.S. Parent Application or PCT Parent Number | Parent Filing Date (MM/DD/YYYY) | STATUS (Check one) PATENTED | PENDING | ABANDONED |
|---|---|---|---|---|
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**POWER OF ATTORNEY:** As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the U.S. Patent and Trademark Office connected therewith. (List name and registration number)

| Send Correspondence to: | Direct Telephone Calls to: |
|---|---|
| | James P. RIEK<br>919-483-8022 |

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

| | | | | |
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| | INVENTOR'S SIGNATURE | Signature | | Date: |
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| 3 | POST OFFICE ADDRESS | POST OFFICE ADDRESS | CITY | STATE & ZIP CODE/COUNTRY |